REMARKS

Claims 1-7, 9-13, and 15-33, of which claims 1, 5, 18, 28, and 31 are currently amended and claims 32-33 are new, appear in this application for the Examiner's review and consideration. Claims 28 and 31 are amended to more particularly define the invention under 35 U.S.C. § 112, second paragraph. Claim 5 is amended as being directed to an embodiment. Claims 1 and 18 are amended to correct typographical errors. New claims 32-33 are added as being directed to a preferred embodiment.

Support for the amendments is found throughout the original specification, including the drawings. For example, the specification discloses that the needle has "an injecting tip 21 extending beyond second end 18 of tube 14 that can be inserted into the person receiving the injection" (p. 4, lines 9-12; p. 6, lines 12-15) as recited in claim 5. The specification and drawings support the new recitations in claims 28 and 31 regarding the fixed association of the needle prior to firing the injector. Also, the drawings illustrate the first stopper configuration having a proximal portion in sealing contact against the tube in lumen and a distal portion protruding distally from the proximal portion and spaced from tube in the lumen and disposed and configured to be pierced by the piercing end of the needle, as recited in claim 32, and the needle being fixed in a hub received within the tube, and the distal portion of the first stopper is configured to be received within the hub when pierced by the piercing end of the needle, as recited in claim 33 (see FIGS. 1-10). As no new matter is introduced, entry of the amendments is warranted at this time.

Claims 1-6, 9-10, 12-13, 16-20, 22-27, and 30 are rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,968,302 to Schluter et al. Claims 1-6, 9-10, 12-13, 16-20, 22-28, and 30-31 are rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,258,713 to Wardlaw. Claims 7, 11, 15, 21, and 29 are rejected under 35 U.S.C. § 103(a) as obvious over Schluter in view of U.S. Patent No. 5,865,799 to Tanaka et al. Applicant respectfully traverses all rejections.

Schluter and Wardlaw are both directed to a type of injector that are well known as "automatic hypodermic injectors" or "autoinjectors." In Schluter, the device "surrounds an injection or hypodermic needle" (1:6-11), and the needle is movable by the lifting element of the device and has cannula inlet opening for the injection substance in the region of its drive-side end (1:11-14). Similarly, Wardlaw discloses an "automatic disposable hypodermic syringe,"

having a retracted needle driven by a spring (Abstract; 2:25-28). As persons of ordinary skill in the are know, an autoinjector is a traditional hypodermic injector that includes a mechanism for automating the driving of the injector, in a way that mimics a hypodermic syringe injection that is powered by hand. Autoinjectors thus employ a relatively slow injection, typically lasting several seconds, and deposit the injected medicament in the same manner as would a hand-powered hypodermic syringe: the medicament is deposited in a bolus at the tip of the needle due to the slow and low-powered flow of the medicament. The characteristics of this medicament delivery are very different from that provided by a jet injector.

By contrast, claims 1, 17, 18, and 30 recite a jet injector. A jet injection is structurally and functionally different from an autoinjector. A person having ordinary skill in the art would have understood a "jet injector" to be a particular class of injector that injects medicament by creating a high speed jet of the medicament that is powerful enough to penetrate the tissue of the patient to a significant distance beyond the exit of the injector. Achieving such depth of penetration is not merely a matter of including a higher energy source, but requires significant structural elements that are different from those of a hypodermic injector.

Specifically, a jet injector requires structural features that are different from those in autoinjectors, to provide a high-energy, high-pressure jet of medicament, such as firing and trigger mechanisms to generate the short duration, high-power firing stroke to generate sufficient pressure to drive the fluid out in a sufficiently powerful jet. These features include, for instance, a substantially more powerful and faster energy source and firing mechanism to drive the plunger when the injector is fired with a sufficiently elevated force and speed to generate the jet, a carefully dimensioned and configured jet nozzle to efficiently form the high speed jet, as well as a significantly more robust medicament container and supporting structure to contain the elevated pressures and withstand the shock produced by the rapid and powerful firing of the jet injector. Because of the high speed and pressure requirements for jet injectors, they are not powered by pressing directly on a plunger by hand, and the firing mechanism thus does not mimic a hand-powered injector. Consequently, a jet injector has very different dispersion characteristics of the medicament into the tissue of the patient and provides must faster absorption of the medicament compared to a hypodermic injector, including autoinjector.

Claim 5 recites that the injecting tip of the needle is configured for insertion into a patient who is receiving the injection. There are several types of jet injectors, including needle-

free and needle-assisted jet injectors. Needle-assisted jet-injectors use a needle to make the initial penetration but provide a jet that is powerful enough to penetrate deeper into the tissue from the needle, instead of merely being deposited as a bolus at the tip as in hypodermic injection. An example of a needle-assisted jet injector is disclosed in U.S. Patent No. 6,056,716 to D'Antonio et al., which shows needle-assisted jet injectors (FIGS. 9C, 9E-9H), a needle-free jet injector (FIG. 9D), and a conventional hypodermic needle injector (FIG. 9A).

Accordingly, there is no disclosure or suggestion of a jet injector in Schluter and Wardlaw, and these references do not anticipate claims 1, 17, 18, and 30.

The cited references also do not render claims 1, 17, 18, and 30 obvious, alone or in combination. Schluter and Wardlaw are directed to autoinjectors. Tanaka is also directed to a conventional hypodermic needle and syringe. In particular, Tanaka discloses a pre-filled syringe capable of separate storage of different substances before use by using a movable plug.

As explained above, hypodermic injectors and jet injectors significantly differ, both structurally and functionally. Because of their different structural and operational requirements, hypodermic injectors disclosed in the cited references are not readily modifiable to be jet injectors. Compared to a hypodermic injector, a jet injector requires a significantly more robust medicament chamber and supporting structure to contain and withstand the elevated pressures and the shock produced by the rapid and powerful firing. Hence, a hypodermic injector cannot reliably be used for jet injection.

Therefore, with respect to claims 7, 11, 15, 21, and 29, the combination of Schluter and Tanaka does not render the claims obvious. Because both references are directed to hypodermic injectors and do not disclose or suggest a jet injector, alone or in combination, it would not have been obvious to one of ordinary skill in the art to provide the jet injector of claims 7, 11, 15, 21, and 29 in view of these references.

Accordingly, none of the cited references, either alone or in combination, discloses or suggests a jet injector, and the present claims are not obvious in view of these references. In view of the above, all rejections under 35 U.S.C. §§ 102(b) and 103(a) should be withdrawn.

Additionally, the dependent claims are further allowable over the cited prior art as including additional recitations that are further distinguished from the prior art.

For example, claims 28 and 31 recite that the needle is in fixed association with the second end of the tube prior to firing the injector. This feature is not disclosed or suggested by Schluter and Wardlaw, in which retractability of the needle is an important part of the disclosed autoinjectors. The feature enables greater precision and allows easier maintenance of needle alignment in a jet injection. The Examiner argued that the needle of Schluter becomes fixed after the injection, whereas the present claims 28 and 31 specify that the fixed association is before the injection, in which case there is still medicament left in the cartridge.

Pursuant to the recommendation in the office action to include a claim that is directed to the shape of the stoppers, claims 32 and 33 have been added. These claims recite a configuration for which there is no teaching or suggestion in the cited references. Thus, claims 32 and 33 are believed to be further allowable over the prior art of record.

Finally, while the Office Action states that the previous rejection of claim 28 under Wardlaw has been withdrawn (Office Action, p. 5), it includes this claim in the listing of claims rejected as anticipated by Wardlaw (Office Action, p. 3). Appropriate correction is respectfully requested.

In view of the foregoing, the entire application is now believed to be in condition for allowance, early notice of which would be appreciated. Should the Examiner not agree, then a personal or telephonic interview is respectfully requested to discuss any remaining issues in an effort to expedite the allowance of this application.

Respectfully submitted,

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